



**VIA FEDERAL EXPRESS**

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

Ref: Customs Entry No.: 336-2327304-4/002  
Product: Pumps (Components)

**WARNING LETTER**

**FLA-01-16**

November 17, 2000

Jenny Leach, Manager  
Baxter Health Care  
One Baxter Parkway  
Deerfield, Illinois 60015

Dear Ms. Leach:

The Food and Drug Administration (FDA) attempted to examine a shipment of pumps (components) offered for entry into the United States by your firm on October 7, 2000, under the above referenced entry number, and found that the entire shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the product was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the pumps (components) which were distributed without a release from FDA (copy enclosed).

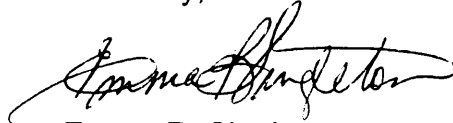
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Jenny Leach  
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Your written reply should be addressed to the Food and Drug Administration,  
Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami,  
Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a large initial "E" and "S".

Emma R. Singleton  
Director, Florida District

Enclosure

cc: Radix Group  
d/b/a Danzas AEI Customs Brokers  
6703 N.W. 7<sup>th</sup> Street  
Miami, Florida 33126

U. S. Customs Service  
P. O. Box 02-5280  
Miami, Florida 33102-5280